IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION, Plaintiff, v. LIQUIDIA TECHNOLOGIES, INC., Defendant.	)	C.A. No. 23-975-RGA-SRF **CONFIDENTIAL – FILED UNDER SEAL**

LETTER TO THE HONORABLE JUDGE RICHARD G. ANDREWS
REGARDING LIQUIDIA'S NDA AND FORM OF JUDGMENT

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Dear Judge Andrews,

Liquidia writes to the Court regarding its NDA No. 213005 ("Liquidia's NDA"). The FDA approved Liquidia's NDA on May 23, 2025 for improving exercise ability in both PAH and PH-ILD. Liquidia launched Yutrepia™ on June 2, 2025, and patients are benefitting from treatment. To ensure continuity of care for PAH patients taking Yutrepia™, Liquidia will file a prior approval supplement to its NDA to remove the PH-ILD indication and revert to its previously adjudicated approval for PAH-only in the event of an adverse opinion from this Court on infringement and invalidity of the '327 patent. We attach a copy of the cover letter for the NDA supplement (Ex. 1) along with the following documents recited in the letter: Dear Healthcare Provider Letter (Ex. 2), Annotated Draft Labeling – Prescribing Information (Ex. 3); and a clean copy of the amended Prescribing Information (Ex. 4).

Liquidia requests a status call with the Court, at its earliest convenience, before issuance of its opinion, to discuss the form of any judgment in this case in view of at least the following:

- This second Hatch-Waxman lawsuit was filed based on an amendment to Liquidia's NDA to add the PH-ILD indication, and the claims of the '327 patent are directed to PH-ILD;
- This Court previously adjudicated Liquidia's PAH-only label for Yutrepia™;
- UTC's pre-trial assertion that it is seeking a judgment pursuant to 35 U.S.C. § 271(e)(4)(A) limited to PH-ILD (*see, e.g.*, Plaintiff's Brief Statement of Intended Proofs, ¶25);
- Liquidia's counterclaims of invalidity and non-infringement of the '327 patent (D.I. 12, ¶¶12-32), and UTC's claims for damages (D.I. 8, Prayer for Relief ¶5); and
- The potential adverse consequences for patients in the event their access to Yutrepia™ is disrupted in view of Yutrepia's™ unique product profile.

Counsel for Liquidia is available at the Court's convenience.

Respectfully submitted,

/s/ Nathan R. Hoeschen

Nathan R. Hoeschen (No. 6232)

cc: Clerk of the Court (by CM/ECF)
All counsel of record (by CM/ECF & Email)